

REMARKS

Claims 31-33, 35-37 and 48-52, are pending in the instant application. Claims 31, 33, 37, and 49 were amended as requested by the Office to remove minor informalities regarding species election. Claims 61-71 were added to provide claims of various scope encompassed by the present invention; said claims are supported throughout the specification and original claims (e.g., including claims 31-33, 35-37 and 48-52). No new matter was added by these amendments. A marked-up version of the changes made to the claims by the current amendment, "Explanation Of Amendments With Markings," is provided. An Appendix with the instant claim set is provided for the Examiner's convenience, and shall not be construed as submission of a re-presented claim set under 37 CFR §1.121.

A. Objections Addressed from July 11, 2002 Office Action (OA)

(1) Objection of claims 31-33, 37, 49, 50, and 52 due to Minor Informalities

Claims 31-33, 37, 49, 50, and 52 were objected to because "these claims recite an unelected subject matter (an amino acid sequence). Appropriate correction is required." (OA, p. 4) Applicant has amended the claims 31, 33, 37, and 49 to delete the recitation of a non-elected species pertaining to SEQ ID NO:47, and references to IL-13Ra (SEQ ID NO:82). Applicant notes that claims 32, 50 and 52 were not subject to species election and were therefore not amended; it is unclear to Applicant why these claims were objected to as reciting unelected subject matter. The instant claims recite the elected species. Consequently, this objection should be properly withdrawn.

B. Rejections Addressed from July 11, 2002 Office Action (OA)

(1) Rejection of claims 31 and 35 under 35 U.S.C. § 102(e)

Claims 31 and 35 were rejected under 35 U.S.C. §102(e) as being anticipated by Novak, et al., (US Patent No. 6,307,024, October 23, 2001; filed March 9 2000). The Office states that claims 31 and 35 were rejected under 35 U.S.C. § 102(e) because "Novak et al., teach exactly the same Zalpha11 cytokine receptor recited by the instant claims...The Zalpha11

cytokine receptor, by its nature forms a heterodimeric or multimeric receptor complex.” (OA, p. 3) Applicant respectfully traverses this rejection.

Under 35 U.S.C. §102(e), for a prior reference to anticipate, every element of the claim must be included in a single reference. Not every element of the claim is included in the Novak et al. reference; therefore, it does not anticipate the claims. Moreover, for a limitation to be considered “inherent,” the single reference “must describe and enable the invention, including all the claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art, and that its existence was recognized by persons of ordinary skill in the field of the invention ... *An inherent limitation is one that is necessarily present; invalidation based on inherency is not established by ‘probabilities of possibilities.’*” (*Elan Pharmaceuticals Inc. v. Athena Neurosciences, Inc.* 304 F.3d 1221, 1228 (Fed Cir. 2002); emphasis added) The Novak et al. reference does not teach “with sufficient clarity and detail to establish that the subject matter” i.e., zalpha11 receptor heterodimers and multimers, “already existed in the prior art,” and in fact teaches nothing about zalpha11 heterodimers and multimers, but rather teaches away from them in that that zalpha11 monomeric and homodimeric receptors act to bind or block the zalpha11 Ligand, and are capable of signaling in the presence of zalpha11 Ligand; that is the reference teaches that limitation of zalpha11 heterodimeric and multimeric receptors is not one that is necessarily present, and therefore invalidation based on inherency is not established by the reference. Because the reference does not teach zalpha11 receptor heterodimers or multimers, it does not teach every element of the claims. Nor does the reference teach or suggest that The Zalpha11 cytokine receptor, by its nature forms a heterodimeric or multimeric receptor complex. Therefore the reference cannot anticipate the claimed invention. Consequently, the rejection of instant claims 31 and 35, and as it may apply to newly added claims 61-71, under 35 U.S.C. §102(e) should be properly withdrawn.

(a) Not every element of the claimed invention is disclosed in the cited reference.

Claims 31 and 35 were rejected under 35 U.S.C. §102(e) as being anticipated by Novak, et al., (US Patent No. 6,307,024, October 23, 2001; filed March 9 2000). Applicant traverses this rejection as applied to instant claims 31 and 35, and as it may apply to newly added claims 61-71.

Under 35 U.S.C. §102(e), for a prior art reference to anticipate a claim, every element of the claim must be included in a single reference. As described below, the instant

claims are not anticipated by Novak et al., because not all elements within the claims are disclosed in the reference, nor does the zalpha11 cytokine receptor by its nature form a heterodimeric or multimeric receptor complex, as detailed in part B(1)(b) below. The heterodimeric or multimeric polypeptides of the present invention are not disclosed and hence the reference cannot anticipate the invention.

Claims 31 and 35 are directed to soluble receptor polypeptides comprising SEQ ID NO:6, and further contain the limitation of heterodimeric or multimeric receptor. Although Novak et al., does disclose the zalpha11 receptor, it does not teach zalpha11 heterodimers, multimers, nor that said receptor can form a multimeric or heterodimeric receptor complex, which are essential elements of the claimed invention. The reference is silent in regards to these essential elements of the claimed invention, and provides no disclosure or teaching of zalpha11 receptor heterodimers, multimers, or that said receptor can form a multimeric or heterodimeric receptor complex. In Novak et al., other than monomeric or homodimeric zalpha11 receptors, the only allusion to any other zalpha11 receptor subunit teaches away from zalpha11 heterodimeric and multimeric receptors when discussing ““beta” type receptor, zalpha11. . . no receptor subunit corresponding to IL-2R α has yet been identified.” (Novak et al., column 8, lines 12-15). This passage in Novak et al., teaches away from zalpha11 receptor heterodimers, multimers, or that said receptor can form a multimeric or heterodimeric receptor complex. In addition, Novak et al. clearly demonstrate that the zalpha11 receptor can bind zalpha11 Ligand, and block the activity of the zalpha11 Ligand as a monomeric or homodimeric receptor (see Novak et al., Examples 11, 12, and 17 (describing binding assays and competitive inhibition by soluble zalpha11 monomeric receptors), columns 64-65, and 69) and can signal as a homodimeric receptor in proliferation assays (see Novak et al., Examples 1-2 (showing signaling by zalpha11 intracellular domain in cell-based proliferation assay), columns 46-48; Novak et al., Examples 3-5 (showing signaling by zalpha11 full-length receptor in cell-based proliferation assay), columns 48-50). Novak et al., demonstrates that zalpha11 receptor may act as a monomeric or homodimeric receptor, while being silent about whether zalpha11 receptor heterodimers or multimers can exist, or that said receptor can form a multimeric or heterodimeric receptor complex. In addition, although it is known in the art of class I cytokine receptors that

they may act as homodimers or heterodimers, or multimers, however, it is also well known that such receptor structure depends on the individual cytokine receptor; that is, a possibility or suggestion as to whether a cytokine receptor *may* act as a heterodimer or multimer is not clear evidence to be considered to anticipate the heterodimeric and multimeric receptors of the present invention. The essential elements of zalpha11 heterodimeric and/or multimeric receptors, are absent in Novak et al.. Therefore, the reference cannot anticipate the claimed invention. Consequently, Applicant respectfully requests that rejection 35 U.S.C. §102(e) of claims 31 and 35, and as may apply to newly added claims 61-71 be withdrawn.

Since this single Novak et al., reference does not teach every element of the claimed invention, it cannot anticipate the invention. Consequently, Applicant respectfully requests that rejections of instant claims 31 and 35, and as it may apply to newly added claims 61-71, under 35 U.S.C. §102(e) be withdrawn.

(b) There is no clear evidence that zalpha11 cytokine receptor by its nature forms a heterodimeric or multimeric receptor complex, in fact Novak teaches that heterodimeric or multimeric zalpha11 cytokine receptors are not necessary

As discussed above, Novak does not provide clear evidence that zalpha11 cytokine receptor by its nature forms a heterodimeric or multimeric receptor complex. In fact, it teaches that monomeric and homodimeric receptors are functional to bind Ligand, antagonize ligand, and to signal as receptors in proliferation assays. The Office does not cite any reference that demonstrates a necessity for zalpha11 heterodimeric or multimeric complexes. The simple knowledge that class I cytokine receptors *may* form heterodimeric or multimeric complexes is merely based on possibility or probability, and is not clear evidence that zalpha11 cytokine receptor by its nature forms a heterodimeric or multimeric receptor complex. In fact, Novak et al., clearly shows function of monomeric and homodimeric zalpha11 receptors demonstrating that zalpha11 heterodimeric or multimeric complexes are not necessary for function of the zalpha11 receptor, and hence cannot form a basis for inherency. Consequently, Applicant respectfully requests that rejections of instant claims 31 and 35, and as it may apply to newly added claims 61-71, under 35 U.S.C. §102(e) be withdrawn.

Applicants maintain their position that the Office has failed to establish a *prima facie* case of unpatentability under Section 102. Claims 31 and 35 are drawn to heterodimeric and multimeric zalpha11 receptors. Novak et al. does not disclose heterodimeric and multimeric zalpha11 receptors. The standard for anticipation (lack of novelty) under Section 102 is one of strict identity. To anticipate a claim, a single reference must contain all its essential elements. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81, 90 (Fed. Cir. 1986) (“It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention, and that such a determination is one of fact.”); *In re Donohue*, 766 F.2d 531, 226 USPQ 619, 621 (Fed. Cir. 1985) (“an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.”); *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986) (“Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference.”). To anticipate a claim, a prior art reference must disclose every feature of the claimed invention, either explicitly or inherently. *Glaxo v. Novopharm, Ltd.*, 334 USPQ2d 1565 (Fed. Cir. 1995).

Further, to serve as an anticipation when a reference is silent about the alleged inherent characteristic, such as in the case of Novak et al., such gap in the reference may be filled by extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily (i.e., always) present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. *In re Oelrich*, 40 USPQ 323 (C.C.P.A. 1981); *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746 (Fed. Cir. 1991). Inherency must be certain. *Ex parte Cyba*, 155 USPQ 756, 757 (Bd. Pat. App. Int. 1966). The single reference “must describe and enable the invention, including all the claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art, and that its existence was recognized by persons of ordinary skill in the field of the invention ... *An inherent limitation is one that is necessarily present; invalidation based on inherency is not established by ‘probabilities of possibilities.’*” (*Elan Pharmaceuticals Inc. v. Athena Neurosciences, Inc.* 304 F.3d 1221, 1228 (Fed Cir. 2002); emphasis added)

Because Novak et al. does not explicitly disclose heterodimeric and multimeric zalpha11 receptors, the rejection cannot be sustained unless the claimed subject matter is inherent in the cited art. However, that is not the case. Novak et al., teaches that monomeric and homodimeric receptors are functional to bind Ligand, antagonize ligand, and to signal as receptors in proliferation assays. By showing the function of monomeric and homodimeric zalpha11 receptors Novak et al., demonstrates that zalpha11 heterodimeric or multimeric complexes are not necessary or inherent for function of the zalpha11 receptor, and hence cannot form a basis for inherency. “An inherent limitation is one that is necessarily present.” (*Elan Pharmaceuticals Inc. v. Athena Neurosciences, Inc.* 304 F.3d 1221, 1228 (Fed Cir. 2002)) The missing descriptive matter, i.e., zalpha11 heterodimeric or multimeric structure, is not “necessarily (i.e., always) present in the thing described in the reference,” and it would *not* be so recognized by persons of ordinary skill in the art, especially in light of the functionality of homodimeric and monomeric zalpha11 receptors described in the reference. Thus, the certainty necessary to establish unpatentability is lacking from the Novak et al. reference.

As such, since this single Novak et al. reference does not teach every element of the claimed invention either explicitly or inherently, it cannot anticipate the invention. Consequently, Applicant respectfully requests that rejections of instant claims 31 and 35, and as it may apply to newly added claims 61-71, under 35 U.S.C. §102(e) be withdrawn.

(2) Rejection of claims 31-33, 35, 37, and 48-52 under 35 U.S.C. § 102(a)

Claims 31-33, 35, 37, and 48-52 were rejected under 35 U.S.C. §102(a) as being anticipated by Presnell et al. (WO 00/17235, March 30, 2000).¹ Applicant respectfully submits the enclosed declarations under 37 CFR §1.131 as evidence that the Presnell, et al. reference is not available as prior art under 35 U.S.C. §102(a). As such, Applicant requests that the rejection of claims 31-33, 35, 37, and 48-52, and as may apply to newly added claims 61-71, be properly withdrawn.

¹ Applicants have redacted dates from the Exhibits of the Rule 131 declaration as allowed under section 715.07 of the Manual of Patent Examining Procedure, 8th addition (August 2001).

In particular, Applicant presents a Declaration under 37 CFR §1.131 which shows that the inventors of the above-referenced application conceived of and reduced to practice the subject matter described in claims 31-33, 35, 37, and 48-52 before March 30, 2000. The Presnell et al., reference is, therefore, not available as prior art under 35 U.S.C. §102(a).

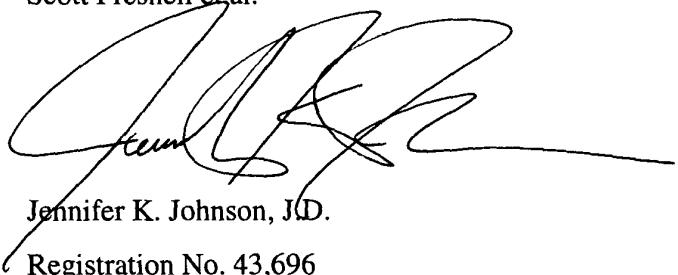
The Office will note that five of the six named inventors have executed the Rule 131 Declaration. The Sixth inventor, Cindy A. Sprecher has left the company and has communicated today, after several unsuccessful electronic and telephonic communications over the past week, that she is currently unavailable to receive or send facsimiles at her forwarding address; thus she is unable to review and execute the Rule 131 Declaration in a timely manner. Although she may become available in the future, obtaining her review and execution of the Rule 131 Declaration is not practicable for the purposes of timely filing a response by the statutory deadline for filing a response to the pending Office Action. Accordingly, Applicant submits that the Rule 131 Declaration, executed by the 5 inventors is sufficient, because Cindy A. Sprecher is *unavailable* for executing the declaration, and because the declaration, although signed by fewer than all joint inventors, evinces conception and reduction to practice of the subject matter described in the presently pending claims. (MPEP 715.04.) Moreover, for the completion of the record, Applicant will send via U.S. Mail to Cindy A. Sprecher the Rule 131 Declaration for her review and execution and will forward the returned executed copy to the Office in a separate communication at the earliest opportunity.

In view of the declarations and remarks above, Applicant respectfully requests that rejections of instant claims 31-33, 35, 37, and 48-52, and as it may apply to newly added claims 61-71, under 35 U.S.C. §102(a) be withdrawn.

Early reconsideration and allowance of the pending claims is respectfully requested. If the Patent Examiner believes that a telephone interview would expedite prosecution of this patent application, please call the undersigned at (206) 442-6676.

Respectfully Submitted,

Scott Presnell et al.



Jennifer K. Johnson, J.D.
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Enclosures:

Amendment Fee Transmittal (in duplicate)
Petition and Fee for 3 Month Extension of Time (in duplicate)
Explanation of Amendments with Markings (3 pages)
Appendix (4 pages)
Declaration Under 37 CFR § 1.131 (7 pages); and Signature page showing James W. West executed Declaration via FAX (1 page)
Exhibit 1- Copies of pages/figures from draft manuscript (3 pages)
Exhibit 3 - Copies of pages 42 and 103; and 130, 138-142 from Notebooks (8 pages)
Exhibit 3 - Copies of pages 36-41 from Notebook (6 pages)
Copies of 2 references
Postcard



**EXPLANATION OF AMENDMENTS WITH MARKINGS TO SHOW CHANGES
MADE**

IN THE CLAIMS:

Please amend the following claims:

31. (Amended) An isolated soluble receptor polypeptide comprising a sequence of amino acid residues as shown in SEQ ID NO:6, wherein the soluble receptor polypeptide forms a heterodimeric or multimeric receptor complex; and

wherein the heterodimeric or multimeric receptor complex binds a ligand comprising a polypeptide of SEQ ID NO:10 ~~or SEQ ID NO:47~~, or antagonizes the ligand activity.

33. (Amended) An isolated polypeptide according to claim 31, wherein the soluble receptor polypeptide forms a heterodimeric or multimeric receptor complex comprising a soluble IL-2R γ receptor polypeptide (SEQ ID NO:4) ~~or a soluble IL-13 α' receptor polypeptide (SEQ ID NO:82)~~.

37. (Amended) An isolated heterodimeric or multimeric soluble receptor complex according to claim 35, further comprising a soluble IL-2R γ receptor polypeptide (SEQ ID NO:4) ~~or a soluble IL-13 α' receptor polypeptide (SEQ ID NO:82)~~.

49. (Amended) An isolated heterodimeric receptor complex according to claim 48, wherein the heterodimeric receptor complex binds a ligand comprising a polypeptide of SEQ ID NO:10 ~~or SEQ ID NO:47~~, or antagonizes the ligand activity.

Please add the following new claims:

-- 61. An isolated heterodimeric receptor complex consisting of two soluble receptor subunits, wherein the first soluble receptor subunit consists of a soluble receptor polypeptide comprising a sequence of amino acid residues as shown in SEQ ID NO:6, and the

second receptor subunit consists of a soluble receptor polypeptide comprising soluble IL-2R γ receptor polypeptide (SEQ ID NO:4).

62. An isolated heterodimeric receptor complex according to claim 61, wherein the heterodimeric receptor complex binds a ligand comprising a polypeptide of SEQ ID NO:10 or antagonizes the ligand activity.

63. An isolated heterodimeric receptor complex according to claim 61, wherein at least one of the soluble receptor subunits further comprises an affinity tag, label, chemical moiety, toxin, biotin/avidin label, radionuclide, enzyme, substrate, cofactor, inhibitor, fluorescent marker, chemiluminescent marker, toxin, cytotoxic molecule or an immunoglobulin Fc domain.

64. An isolated heterodimeric receptor complex according to claim 61, wherein at least one of the soluble receptor subunits further comprises a transmembrane domain.

65. An isolated heterodimeric receptor complex according to claim 64, wherein the transmembrane domain is from a class I cytokine receptor.

66. An isolated heterodimeric receptor complex according to claim 61, wherein at least one of the soluble receptor subunits further comprises a transmembrane domain, and an intracellular domain from a cytokine receptor.

67. An isolated polypeptide according to claim 66, wherein the intracellular domain is from a class I cytokine receptor.

68. An isolated heterodimeric receptor complex according to claim 61, wherein both of the soluble receptor subunits further comprise a transmembrane domain.

69. An isolated heterodimeric receptor complex according to claim 68, wherein the transmembrane domain is from a class I cytokine receptor.

70. An isolated heterodimeric receptor complex according to claim 61, wherein both of the soluble receptor subunits further comprise a transmembrane domain, and an intracellular domain from a cytokine receptor.

71. An isolated polypeptide according to claim 70, wherein the intracellular domain is from a class I cytokine receptor.--